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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,810	04/12/2004	Jennifer Lynne Reed	IL500US	5467

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JOHNATHAN KLEIN-EVANS
ONE MEDIMMUNE WAY
GAITHERSBURG, MD 20878

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
12/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,810	REED, JENNIFER LYNNE	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the claim amendments filed on 10/31/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8-11,15-25,27,28 and 37-40* is/are pending in the application.

4a) Of the above claim(s) *11, 16, 17, 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3-5, 8-10, 15, 18-21, 23-25, 27, 28 and 37-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note: Applicant's amendments filed on 10/31/2007 have been made of record. Upon further consideration of new and amended claims, the Examiner finds that pending claims require a restriction election.

It is noted to Applicants that in response to Restriction/Election of 2/22/2007, applicants elected the species "influenza virus." Claims 11, 16, 17, and 22 were withdrawn for reciting a non-elected invention (i.e., RSV) in the previous office action of 5/1/2007. Therefore, claims 16, 17 and 22 are non-compliant because they are not identified by a proper claim amendment (currently withdrawn).

Status of Amendments, And/Or Claims

Claims 2, 6-7, 12-14, 26 and 29-36 are cancelled.

Claims 1, 3-5, 8-11, 15-25, 27, 28, 37-40 are pending.

Claims 11, 16, 17, 22 are withdrawn for reasons of record in the previous office action of 5/1/07.

Claims 1, 3-5, 8-10, 15, 18-21, 23-25, 27, 28 and 37-40 are restricted.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-5, 8-10, 15, 18-21, 23-25, 27, 28 and 37-40 as drawn to a method of treating or ameliorating a respiratory infection or a symptom thereof, in a human subject suffering therefrom, said method comprising an antagonist or an antibody or fragment thereof comprising a VH CDR1 comprising the amino acid sequence of SEQ ID NO:26,

a VH CDR2 comprising the amino acid sequence of SEQ ID NO:64, a VH CDR3 comprising the amino acid sequence of SEQ ID NO:3, a VL CDR1 comprising the amino acid sequence of SEQ ID NO:65, a VL CDR2 comprising the amino acid sequence of SEQ ID NO:66, and a VL CDR3 comprising the amino acid sequence of SEQ ID NO:20, classified in class 514, subclass 44.

II. Claims 1, 3-5, 8-10, 15, 18-21, 23-25, 27, 28 and 37-40, as drawn to a method of treating or ameliorating a respiratory infection or a symptom thereof, in a human subject suffering therefrom, said method comprising an antagonist or an antibody or fragment thereof comprising a VH domain comprising the amino acid sequence of SEQ ID NO: 27 and a VL domain comprising the amino acid sequence of SEQ ID NO: 28, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of treating or ameliorating a respiratory infection or a symptom thereof, in a human subject suffering therefrom, said method comprising an antagonist or an antibody or fragment thereof comprising a VH CDR1 comprising the amino acid sequence of SEQ ID NO:26, a VH CDR2 comprising the amino acid sequence of SEQ ID NO:64, a VH CDR3 comprising the amino acid sequence of SEQ ID NO:3, a VL CDR1 comprising the amino acid sequence of SEQ ID NO:65, a VL CDR2 comprising

the amino acid sequence of SEQ ID NO:66, and a VL CDR3 comprising the amino acid sequence of SEQ ID NO:20 (group I) and the method of treating or ameliorating a respiratory infection or a symptom thereof, in a human subject suffering therefrom, said method comprising an antagonist or an antibody or fragment thereof comprising a VH domain comprising the amino acid sequence of SEQ ID NO:27 and a VL domain comprising the amino acid sequence of SEQ ID NO:28 are all unrelated as they comprise distinct steps and utilize different antibody fragments, which demonstrates that each method has a different mode of operation. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I and II are patentably distinct.

This application contains claims directed to the following patentably distinct species:

Species Election for Group I and II

Respiratory infections:

Claims 9 –11 list a number of respiratory infections (a viral, a bacterial or a fungal infection).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed infection for example, a viral infection, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 3 are the examples of a generic claim.

Respiratory diseases:

Claims 25, 28 and 40 list a number of diseases (e.g., bronchopulmonary dysplasia, congenital heart disease, cystic fibrosis, acquired immunodeficiency or congenital immunodeficiency).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed disease for example, cystic fibrosis, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 3 are the examples of a generic claim.

Type of additional therapy:

Claims 15, 18-21 list a number of additional therapies (e.g., an antibiotic, an anti-viral agent, an antifungal, anti-RSV, an anti-histamine, a leukotriene modifier or a mast cell modulator).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, for example leukotriene modifier, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 3 are the examples of a generic claim.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species and that each species is different from other species in its structure and function relationship such as anti-fungal agent is very different than an anti-viral agent. In addition, these species are not obvious variants of each other based on the current record.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and (ii) the species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (iii) identification of the claims encompassing the elected invention and the elected species.**

The election of an invention and the species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention and species.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions or the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions or the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant elects Group I or II, one species from Respiratory infection group, one species from the Respiratory disease group and one species from the therapy group must be identified to be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
29 November 2007
Fax: 571-273-2922

/Robert Landsman/
Primary Examiner, Art Unit 1647